ETS RISK ASSESSMENT

The U.S. Environmental Protection Agency (EPA) has been working the last couple of years on a risk assessment of environmental tobacco smoke (ETS), or "passive smoking," as it is sometimes called.

Ethically and scientifically, this risk assessment seems to fall short of the EPA's own guidelines and procedures for risk assessment.

An objective, dispassionate appraisal of the scientific evidence makes total smoking bans seem both inappropriate and scientifically insupportable. More importantly, such an examination illuminates the need for stricter enforcement of risk assessment guidelines in order to ensure the integrity of the risk assessment process.

Following are some examples of how this particular risk assessment has failed to meet the EPA's own guidelines and standards.

First, a risk assessment is designed to weigh all scientific evidence relevant to a substance under scrutiny. In the case of ETS, several important studies have not been included in the "meta-analysis" the EPA used to calculate risk. Meta-analysis is

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a procedure for combining the results of several studies in an attempt to estimate a statistical risk.

The first study to be excluded was an unpublished Yale dissertation by a physician who was earning a doctorate degree in epidemiology. The dissertation, which was published recently in The New England Journal of Medicine, reported no association between lung cancer in nonsmoking women and spousal smoking, as is being claimed in the EPA's draft risk assessment.

The EPA knew about the Yale study - and, in fact, mentions the study in the draft risk assessment - but does not include it quantitatively. That means the numbers produced by the study were not combined in the meta-analysis the EPA performed to try to calculate risk. Researchers at the EPA have said the study was excluded because the raw data were not available.

Meanwhile, the EPA did include one study - considered the "flagship" for the risk assessment - which was sharply criticized by the EPA's Science Advisory Board (SAB), the panel summoned to review the draft risk assessment. One SAB member urged that this study, by Dr. Tasheki Hirayama, be discarded because of methodological problems. The only way to resolve those problems would have been to examine the raw data, but it seems Dr. Hirayama destroyed the data.

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Three other recent studies have surfaced since the EPA drafted its risk assessment. To date none has been included in the meta-analysis. All three of these studies - including one that is the largest ever conducted on the subject -- report no increased risk of lung cancer among nonsmoking women married to smoking husbands. Addition of the three studies to the meta-analysis would virtually eliminate a statistically increased risk of disease.

Especially vexing is the fact that the largest of these studies was co-authored by a member of the EPA's own Science Advisory Board. This board member - Dr. William Blot of the National Cancer Institute - has yet to mention his study or his findings during discussions of the risk assessment. The study surfaced a couple of months ago upon publication in a scientific journal.

Failure to consider these new studies is contradictory to the stated purpose of the risk assessment, which was to evaluate new research conducted since the U.S. Surgeon General's 1986 report on ETS. This new risk assessment virtually ignored much of the latest research.

This fact was indirectly acknowledged by the SAB chairman, Dr. Morton Lippmann, at the conclusion of the SAB's executive committee meeting. Dr. Lippmann said the risk assessment provided

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no new evidence, but merely confirmed the Surgeon General's earlier report. This is true by virtue of the fact that the new studies were not included. Inclusion of these new studies would have significantly altered the results of the risk assessment.

Another problem with the ETS risk assessment concerns the composition of the Science Advisory Board itself. The SAB panel is supposed to be composed of objective scientists who are qualified by their training to serve, but who are also unbiased relative to the substance being examined.

The SAB panel selected to review the ETS risk assessment was neither objective nor unbiased. Instead, it was composed of scientists who either had publicly announced their positions on the issue or who had participated in the risk assessment itself.

Throughout the risk assessment process, there seems to have been a pattern of disregard for that process. When the risk assessment was first drafted in June 1990, for example, the EPA leaked the contents of the document to the media, prompting a flurry of misleading headlines and news stories. At the same time, the EPA released a draft Guide To Workplace Smoking Policies. This policy guide, ostensibly premised on the risk assessment, was written and released before the review process was even formally begun.

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The policy guide, intended for use by municipal and state governments, essentially recommended banning smoking. The only alternative offered -- to provide separate ventilation systems for smokers -- was relatively moot in light of the prohibitive expense. In any case, what is disturbing about the policy guide is not so much the suggestion that smoking be banned, but that the policy clearly preceded the science.

Finally, the conclusion that ETS poses a risk requiring banning smoking seems excessive and inconsistent with the SAB chairman's most recent appraisal of the risk assessment. Speaking to reporters following the executive committee's meeting, Dr. Lippmann told reporters they were at greater risk driving across town to attend the meeting than they were from exposure to ETS.

At the present time, the draft risk assessment is in the hands of EPA Administrator William Reilly for his review and recommendations. The SAB executive committee forwarded the risk assessment to Mr. Reilly with a qualified endorsement. The committee said that while it concurred with the EPA's judgement, generally, it had "some difficulty" applying the EPA's guidelines to ETS.

In other words, if the EPA guidelines were strictly applied, the risk assessment would fail to establish ETS as a carcinogen.

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Risk assessments must be conducted in a fair and consistent manner in accordance with the EPA's guidelines. Arbitrarily applying these guidelines undermines the intent of the laws that created them and ultimately jeopardizes the public they were designed to protect.

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